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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,270	08/03/2001	Jurgen Kleinschmidt	8484-101-999	3472

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PENNIE & EDMONDS LLP
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New York, NY 10036-2711

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,270

Applicant(s)

KLEINSCHMIDT ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on September 13, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed September 10, 2003 (Paper No. 13) in response to the Office Action of March 11, 2003 is acknowledged and has been entered. Claims 13-27 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The objection of claims 13-27 to because of informalities relating to the AAV abbreviation is withdrawn.

The rejection of claims 13-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendment to the claims. Please note only some of the claim rejections are withdrawn in view of the amendments.

The rejection of claims 21-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for reasons of record.

The rejection of claims 13 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bett et al. (Proceeding of the National Academy of Science, 1994) **is maintained** for reasons of record.

Applicant's response has been fully considered but fails to persuade for the following reasons. In response to applicant's argument that the references fail to show certain features of

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applicant's invention, it is noted that the features upon which applicant relies (i.e., the entire AAV nucleic acid sequence) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claims as written are drawn to an "adeno-associated viral nucleic acid". The "nucleic acid" can be interpreted to relate to single nucleotide (singular) or it could be interpreted to read on the entire adeno associated viral "nucleic acid sequence" (plural more than one nucleic acid). If the claims had been interpreted to read on the entire nucleic acid sequence the claims would have needed to be rejected because there would have been no written description for this in the specification. The specification indicates that the full light AAV sequence is 4680 nt, yet in the examples set forth the AAV sequence only comprises 4235 nt this is a discrepancy of 445 nt. Hence the "adeno-associated viral nucleic acid" that applicants are contemplating is not the entire AAV genome and is less than the entire genome yet there is no limit set on how much less can be considered and still fall within the claimed invention. It is not clear from the specification what part of the AAV genome are not to be included in the "adeno-associated viral nucleic acid". For purposes of the instant rejection the "adeno-associated viral nucleic acid" is interpreted to read on a single (one) nucleic acid and the nucleic acid sequence disclosed in Bett et al. comprise a single nucleic acid in common with AAV so that the disclosed sequence comprises an AAV nucleic acid and the helper nucleic acid sequences. Therefore, the instant invention remains rejected as being anticipated by Bett et al.

The rejection of claims 13, 17-20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bett et al. (Proceeding of the National Academy of Science, 1994) and Colosi (U.S. Patent No. 6,004,797) **is maintained** for reasons of record.

Applicant's response has been fully considered but fails to persuade for the following reasons. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the entire AAV nucleic acid sequence) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claims as written are drawn to an "adeno-associated viral nucleic acid". The "nucleic acid" can be interpreted to relate to single nucleotide (singular) or it could be interpreted to read on the entire adeno associated viral "nucleic acid sequence" (plural more than one nucleic acid). If the claims had been interpreted to read on the entire nucleic acid sequence the claims would have needed to be rejected because there would have been no written description for this in the specification. The specification indicates that the full light AAV sequence is 4680 nt, yet in the examples set forth the AAV sequence only comprises 4235 nt this is a discrepancy of 445 nt between the wild type virus and the portion of the virus set out in example 1, from example 1 it is not clear what is missing from the sequence. Hence the "adeno-associated viral nucleic acid" that applicants are contemplating is not the entire AAV genome and is less than the entire genome yet there is no limit set on how much less can be considered and still fall within the claimed invention. It is not clear from the specification what part of the AAV genome are not to be included in the "adeno-associated viral nucleic acid". For purposes of the instant rejection the

“adeno-associated viral nucleic acid” is interpreted to read on a single nucleic acid and the nucleic acid sequence disclosed in Bett et al. comprise a single nucleic acid in common with AAV so that the disclosed sequence comprises an AAV nucleic acid and the helper nucleic acid sequences.

It would have been obvious at the time the invention was made to use an E1 deleted adenovirus type 5 in a 293 cell to produce recombinant AAV particles. The E1 deleted adenovirus in a 293 cell comprises all the necessary sequences set out in Colosi to produce the recombinant AAV particles, indicating that the combination is suitable for the purpose of producing AAV particles. Therefore, the instant invention is obvious over Bett et al. and Colosi.

Conclusion

Claims 13-27 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

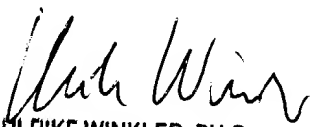
Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.


ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 8/20/04